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(12) PATENT APPLICATION A1

(22) Application date: December 5, 1988. (71) Applicant(s): GARCIA, Alain  
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(30) Priority: (72) Inventor(s):  
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documents: (73) Assignee(s):  
(74) Agent(s):

(54) Replacement of the Nucleus of the Intervertebral  
Disk with a Polyurethane Polymerised In Situ.

(57) The present invention pertains to a process, a device, and a product permitting  
the nucleus of the intervertebral disk to be replaced after annucleation.

The process consists of polymerizing a mixture 7 in the cavity 4, leading to the  
formation of a polymer.

The device is formed by a bag 1 attached to a tube 2. The mixture 7, injected  
into the bag 1, reacts to form a polyurethane.

A device 3 permits the bag 1 to be closed.

The device permits the functions of the intervertebral joint to be restored.

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The present invention pertains to a device permitting part (the nucleus) of the intervertebral disks to be replaced with an implanted material.

A polyurethane (10) is polymerized directly in the cavity (4) created at the time of a nucleotomy or chemonucleolysis.

This device is intended to restore the mobility and absorbing functions of injured disks without implanting a total prosthesis of the intervertebral disk.

The device comprises an airtight polyethylene bag (1) containing no air, which is attached to the end (8) of the tube (2).

Said tube (2) has an end (8) and an end (9).

At its end (8), said tube (2) has a heating resistor (3) permitting said bag (1) to be closed by thermal welding.

Said tube (2) is introduced into the cavity (4) formed by removal of the nucleus by means of a trocar (5).

The approach route is the same as that used for nucleotomy or chemonucleolysis.

A mixture (7) of monomers and catalysts is injected through said tube (2) into the interior of said bag (1) in order to fill up said cavity (4).

After sealing said bag (1) by means of said resistor (3), polymerization takes place in ca. 30 minutes at 37°C. It leads to the formation of a polyurethane (10) according to the formula shown in Figure 3.

One variant consists of injecting microspheres (11) of polyurethane (10) into said bag (1).

Figure 1 shows a section of said tube (2) and said trocar (5).

Figure 2 shows an axial sectional view of the intervertebral disk and the three steps of the in situ polymerization in said cavity (4).

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Figure 3 shows the chemical reaction leading to the formation of polyurethane (10).

Figure 4 shows the variant.

Said bag (1) is formed by an impermeable polyethylene film with a thickness of 0.1 mm. Its volume reaches ca. 2 cm<sup>3</sup> after expansion.

Said tube (2) has a length of 25 cm and a diameter of 3 mm. It may be made of stainless steel.

The chemical reaction leading to the formation of the polyurethane (10) takes place in the following mixture (7):

Hylene V (trademark)	1 NGU
Butanediol 1-4	0.5 OK
Polymog 1000 (trademark)	0.5 OM
Dimethyltin dilaurate	0.02% of the mixture.

The device may be made in the form of a ready-to-use sterile "kit" permitting preheating of the monomers used.

The device according to the present invention is intended to be placed by physicians and surgeons after nucleotomy or chemonucleolysis in order to restore the intervertebral joint function.

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## CLAIMS

1. Surgical device for implanting a prosthesis of an intervertebral disk after nucleotomy or chemonucleolysis and the resulting formation of a cavity (4) in the disk. This device is characterized in that it comprises a tube (2) able to be inserted into a trocar (5). The tube (2) has a front end (8) equipped with an expandable bag (1) and a rear end (9) connected to a means for injecting a product that permits the bag (1) to expand in the cavity (4).

2. Surgical device in accordance with claim 1, characterized in that the product introduced into the bag (1) is a mixture capable of undergoing polymerization or microspheres of polyurethane.

3. Device in accordance with one of the claims 1 and 2, characterized in that the front end (8) of the tube (2) is equipped with a heating means able to induce sealing of the bag (1).

4. Device in accordance with any of the claims 1 through 3, characterized in that the bag (1) is made of polyethylene.

5. Device in accordance with claim 1, characterized in that the mixture capable of undergoing polymerization comprises at least one isocyanate, at least one polyol, and at least one suitable catalyst.

6. Device in accordance with claim 5, characterized in that the mixture of isocyanate, polyol, and catalyst is adapted to undergo polymerization at 37°C in about 30 minutes.

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Figure 1

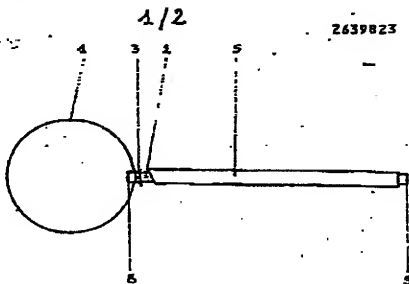
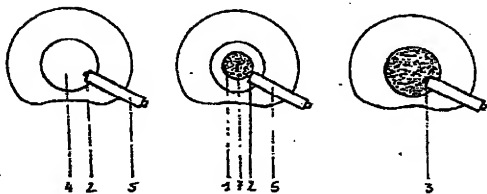


Figure 2



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Figure 3

Hylene V (trademark) 1 NCO	+	Polysag 1000 (trademark) 0.5 OH	+	Butanediol-(1-4) 0.5 OH
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Dimethyltin dilaurate  
0.02% of the mixture



Figure 4

